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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,001	06/28/2005	Ludwig J Weimann	ULT1.LU-25	9034

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,001	WEIMANN, LUDWIG J	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,52-54 and 57-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,52-54 and 57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/05,3/06,12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 6, 2008, has been received and entered.

Claims 15-51 and 55-56 are canceled. Claims 1-14, 52-54, and 57-62 are pending.

Election/Restrictions

Applicant's election with traverse of insulin as the active agent (recited in claims 58-62) in the reply filed on May 6, 2008, is acknowledged. The traversal is on the ground(s) that no one specific substance or agent of the list of species is critical for the operation of the invention. This is found persuasive, thus the species requirement of March 6, 2008, is hereby withdrawn.

Claims 1-14, 52-54, and 57-62 are examined on the merits to the extent they read on the elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is rendered indefinite by the recitation "the micro." Thus, claims 52 and 53 are rejected under 35 U.S.C. 112, second paragraph. It is suggested that "the micro" be replaced with "the microspheres."

Claim 54 is rendered indefinite by the recitation "the spheres," which lacks antecedent basis. It is suggested that "the spheres" be replaced with "the microspheres or nanospheres."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-13, 52, 53, and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Royds et al. (US 5,466,465) (listed on 6/8/05 IDS) in view of Ishihara (US 5,190,766) (listed on 3/30/06 IDS).

Royds et al. teaches a transdermal drug delivery system (abstract), hence a patch. Figure 1 presents in detail a transdermal patch (column 4, lines 30-32). The patch contains a matrix 20 carrying microencapsulated particles of the drug to be delivered (column 4, lines 56-65) and an adhesive layer 16 (column 4, lines 45-48). In the operation of the drug delivery system, the drug leaches from the particles into the matrix 20 for subsequent passage through the skin of the user (column 5, lines 10-12). As the matrix is formulated to absorb several times its own weight in water given the compounds present in the matrix (column 4, lines 56-61), the matrix holding the microcapsules include skin permeation enhancers (as they would foster hydration of the skin area, fostering release and adsorption of the drug, see column 4, lines 53-55).

Royds et al. differs from the claimed invention in that it does not teach that energy, including ultrasonic energy, is used to selectively release the drug from the microcapsules.

Ishihara discloses the controlled release of a drug from a drug carrier or a drug holding structure wherein the drug carrier or drug holding structure is irradiated with a sound wave having a frequency including the resonance frequency of the drug carrier, thereby controlling the release of the drug from the drug carrier (claim 1). A microcapsule having a diameter of not more than about 0.008 mm may be used as the drug carrier (column 9, lines 36-41). Moreover, an ultrasonic wave of 1.5 to 2 MHz (1500 to 2000 kHz) may also be used to release drugs from a microcapsule according to the invention.

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have performed the methods of Ishihara on the transdermal patch of Royds et al. One of ordinary skill in the art would have been motivated to do this since ultrasound radiation according to Ishihara controls the release of drug. Thus, claims 1, 3-6, 8, 9, 13, 52, 53, and 57 are rendered obvious.

Also, claim 7 is rendered obvious because it would have been obvious to the person of ordinary skill in the art to have included multiple drugs in a single patch in order to treat a variety of symptoms. As the film material and the particle diameter affects the optimum resonance frequency (Ishihara, column 10, lines 62-65), different capsules containing different drugs can be selected for release.

Furthermore, it would have been obvious to the person of ordinary skill in the art to have included different drugs in the microcapsules, including those recited in claims 8-12 and 58-62, as it would have achieved the predictable result of drug delivery. Furthermore, as noted in the response filed on May 6, 2008, no one specific substance or agent for drug delivery is critical for the operation of the claimed invention. Thus, claims 8-12 and 58-62 are rendered obvious.

Claims 1-14, 52, 53, and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Royds et al. and Ishihara as applied to claims 1, 3-13, 52, 53, and 57-62 above, and further in view of Zeimer et al. (US 4,891,043).

As discussed above, Royds et al. and Ishihara render claims 1, 3-13, 52, 53, and 57-62 obvious. However, they do not expressly disclose that thermal energy is applied to the patch to release the encapsulated drug from the microcapsules.

Zeimer et al. teaches a system for selectively releasing materials, such as drugs, at a specific site in the body of an animal (abstract). Lipid vesicles containing the drug are irradiated by a laser beam, thereby heating the lipid vesicles and causing them to rupture (column 4, lines 38-40).

At the time the invention was made, it would have been obvious to have controlled the release of the drugs from the microcapsules in the patch disclosed in Royds et al. by the application of thermal energy (laser beam) to the microcapsules. One of ordinary skill in the art would have been motivated to do this since it would have allowed for the control of drug release, increasing the selectivity of drug release. Thus, claims 2, 14, and 54 are rendered obvious.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef